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तम्बाकू एवं तम्बाकू उत्पाद — सिगरेट्स —  
मॉनिटर परिक्षण नमूना अपेक्षाएं एवं प्रयोग  
( पहला पुनरीक्षण )

**Tobacco and Tobacco Products —  
Cigarettes — Monitor Test Piece —  
Requirements and use**  
( *First Revision* )

ICS 65.160

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## FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Tobacco and Tobacco Products Sectional Committee had been approved by the Food and Agriculture Divisional Council.

Smoke yields of cigarettes are routinely analysed for quality control, product development and regulatory compliance by smoking cigarettes on an analytical smoking machine. The smoke yield values should reflect the contribution of only the tobacco blend and cigarette design when smoked under a standard smoking regime, the smoking machine should not play any role in influencing the smoke yields. This is possible only if the analytical processes involved when using a cigarette smoking machine are stable and consistent. To ensure this, the smoking machine and smoking process are monitored regularly by smoking test cigarettes made to very strict specifications within a very narrow range of variation. As the test cigarette is meant only for laboratory purposes and not for human consumption, it is differentiated from normal cigarettes by naming it as monitor test piece.

Monitor test pieces can be manufactured indigenously or obtained from CORESTA (Centre de Coopération pour les Recherches Scientifiques Relatives au Tabac/Cooperation Centre for Scientific Research Relative to Tobacco, Paris; [www.coresta.org](http://www.coresta.org)).

In view of the above, it was considered necessary to set specifications for manufacturing the test pieces as well as a standard method for using the indigenously made test pieces or CORESTA test pieces for monitoring the stability of the smoking machine and smoking process on a regular basis.

This standard was first published in 2015 as identical adoption of ISO 16055 : 2012 'Tobacco and tobacco products — Monitor test piece — Requirements and use'. The ISO standard has since been revised in 2019 to align with the more intensive smoking regimes used in ISO 20778 'Cigarettes — Routine analytical cigarette smoking machine — Definitions and standard conditions with an intense smoking regime' and ISO 20779 'Cigarettes — Generation and collection of total particulate matter using a routine analytical smoking machine with an intense smoking regime'. This revision is being brought out to develop IS 16307 as indigenous standard, while aligning with latest technological advancements in the area and alignment with Intense Smoking Regime of ISO was not found suitable. In formulation of this standard, considerable assistance has been drawn from ISO 16055 : 2019 'Tobacco and tobacco products — Monitor test piece — Requirements and use'.

While formulating this standard, necessary consideration has also been given to the relevant rules and regulations prescribed by the Government of India under the Cigarettes and Other Tobacco Products Act (COTPA), 2003 and the Legal Metrology (Packaged Commodities) Rules, 2011.

The composition of the Committee responsible for the formulation of this standard is given in Annex C.

In reporting the result of a test or analysis made in accordance with this standard, if the final value, observed or calculated, is to be rounded off, it shall be done in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'.

## *Indian Standard*

# TOBACCO AND TOBACCO PRODUCTS — CIGARETTES — MONITOR TEST PIECE — REQUIREMENTS AND USE

( *First Revision* )

### 1 SCOPE

This standard describes the requirements for a monitor test piece, its manufacture as well as its use for monitoring the stability of the analytical processes involved when using a cigarette smoking machine.

### 2 REFERENCES

The standards given below contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of these standards.

| <i>IS No.</i>                           | <i>Title</i>                                                                                                                                                                            | <i>IS No.</i>         | <i>Title</i>                                                                                                                                        |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
|                                         |                                                                                                                                                                                         | 16025 : 2014          | Cigarettes — Determination of nicotine in smoke condensates — Gas-chromatographic method                                                            |
|                                         |                                                                                                                                                                                         | 16042 (Part 1) : 2012 | Cigarettes — Determination of water in total particulate matter from the mainstream smoke: Part 1 Gas-chromatographic method                        |
|                                         |                                                                                                                                                                                         | 16042 (Part 2) : 2021 | Cigarettes — Determination of water in total particulate matter from the main stream smoke: Part 2 Karl Fischer method ( <i>under development</i> ) |
| 15393 (Part 2) : 2003/ISO 5725-2 : 1994 | Accuracy (Trueness and Precision) of measurement methods and results — Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method |                       |                                                                                                                                                     |
| 16022 : 2015                            | Routine analytical cigarette-smoking machine — Definitions and standard conditions                                                                                                      |                       |                                                                                                                                                     |
| 16024 : 2012                            | Cigarettes — Determination of carbon monoxide in the vapour phase of cigarette smoke — NDIR method                                                                                      |                       |                                                                                                                                                     |
| 16121 : 2013                            | Tobacco and tobacco products — Atmosphere for conditioning and testing                                                                                                                  |                       |                                                                                                                                                     |
| 16023 : 2021                            | Cigarettes — Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine ( <i>first revision</i> )                                       |                       |                                                                                                                                                     |

### 3 TERMS AND DEFINITIONS

For the purposes of this document, the following terms and definitions apply.

**3.1 Monitor Test Piece** — Cigarette sample produced for a specific test purpose, validated to fulfil requirements within specified tolerances and intended to be used for laboratory purposes only and labelled to clearly indicate that it is not for human use. Monitor test piece is used to monitor the stability of analytical processes involved when using a cigarette-smoking machine.

A monitor test piece is a sample taken from a batch of cigarettes that show the greatest homogeneity with regard to their physical, chemical and smoke yield characteristics.

**3.2 CORESTA Monitor Test Piece** — Monitor test piece supplied by CORESTA.

**3.3 Analysis Value** — Result, based on the testing of 5 or 20 items (depending on the type of smoking machine used), of a smoking test and analysis carried out in accordance with IS 16023, IS 16024, IS 16025 and IS 16042 (Part 1) [or IS 16042-2/FAD 04 (16062)].

**3.4 NFDPM (Nicotine-Free Dry Particulate Matter)** — A derived value obtained by subtracting the contents of nicotine and water from total particulate matter (TPM) per test piece or cigarette.

**3.5 Smoke Yield** — Contents of NFDPM, nicotine and carbon monoxide per test piece or cigarette.

## 4 REQUIREMENTS

**4.1** The monitor test pieces shall be produced from one production batch.

**4.2** The number of monitor test pieces produced shall be sufficient to cover the needs of a period of at least two years.

**4.3** For reasons of homogeneity, the cut tobacco used shall be taken from one well-mixed batch of a single grade of flue-cured tobacco with no addition of further materials, such as stems, humectants or flavours.

**4.4** The non-tobacco materials used, such as cigarette paper, filters and tipping paper shall be taken from one production batch and strict quality-control measures shall be applied specially during the production of the filters.

Specifications for the production of CORESTA monitor test pieces are to be found in Annex A. The requirements also include a stable yield for carbon monoxide which is best obtained with a non-ventilated filter. Therefore, the recommendation is that the monitor test piece is unventilated. Similar specifications may be adopted for local production of monitor test pieces.

**4.5** The production tolerances on tobacco mass, circumference and draw resistance of the monitor test piece shall be controlled as precisely as possible. It will normally be necessary to increase the quality control measures and to decrease the production machine speed to obtain the required consistency in physical, chemical and smoke yields of the monitor test pieces. Mass control is critical in the production of a reliable monitor test piece. Excessive mass variation contributes to unacceptable variation in smoke yields. The standard deviation of mass of individual monitor test piece must be controlled to below 16 mg. If necessary, monitor test pieces should be selected by mass before smoking.

**4.6** The packaged monitor test pieces shall be stored at a temperature below or equal to +4 °C until they are to be used.

NOTE — Other reference standards in the tobacco field require a storage temperature below –16 °C for reasons of hygiene. Normally, a storage temperature of +4 °C is sufficient for monitor test pieces.

**4.7** The monitor test pieces in a lot shall show consistent values for the puff Nos. and the contents of NFDPM, nicotine and carbon monoxide in their smoke yields. This consistency shall be assessed by means of a

comparative study of sufficient size across participating laboratories and smoking machines.

**4.8** The product design shall ensure that the smoke yields (NFDPM, nicotine and carbon monoxide) are sufficiently high per monitor test piece (approximately 14 mg NFDPM and carbon monoxide, approximately 1.4 mg nicotine) so that the influence from a possible offset in the smoking machine settings can be distinguished from the normal variation of the smoke yields.

**4.9** It is essential to make the monitor test piece clearly distinguishable from commercial cigarettes. The monitor test pieces shall be packed in hinge-lid boxes of 20 labelled with the Sample No. and a text. 'For Laboratory use only' in addition to the regulatory requirements in force.

## 5 TESTING

**5.1** Testing of the lot, including determination of the values for carbon monoxide, NFDPM, and nicotine in the smoke, shall be carried out in accordance with IS 16024, IS 16023, IS 16025 and IS 16042-1 [or IS 16042 (Part 2) the form of an interlaboratory trial run to check the consistency of the monitor test pieces in accordance with 15393 (Part 2). The results are statistically evaluated to ensure acceptably low variation in physical parameters and smoke yields prior to release of the monitor test piece for use. In addition, stored monitor test piece should be tested annually in an interlaboratory study to ensure the consistency of all its essential parameters over long storage.

NOTE — Monitor test pieces for daily routine use may be produced by the individual company for its own purposes. However, for the purposes of interlaboratory comparisons or for comparison of analytical consistency between laboratories, it is advised to use CORESTA monitor test pieces.

**5.2** The smoke yield will normally be based upon the smoking of at least 20 monitor test pieces to set specifications for smoke yield (mean and SD) for the lot and recorded in the data sheet (*see* 6). These values will be used to prepare the control charts for monitoring the stability of the smoking machine and smoking process.

NOTE — CORESTA monitor test piece will have already gone through a multi-laboratory study before being shipped. The data sheet accompanying each consignment of CORESTA monitor test piece will contain all relevant data ready to be used for monitoring purposes.

**5.3** If the smoke values (mean and SD) of the test pieces match with those recorded in the data sheet, the smoking machine and smoking process will be taken as stable. Otherwise the errors will be identified and corrective action taken. Sample cigarettes shall be smoked only on a stable smoking machine.

Figure 1 illustrates the use of monitor test pieces in routine smoking analysis.

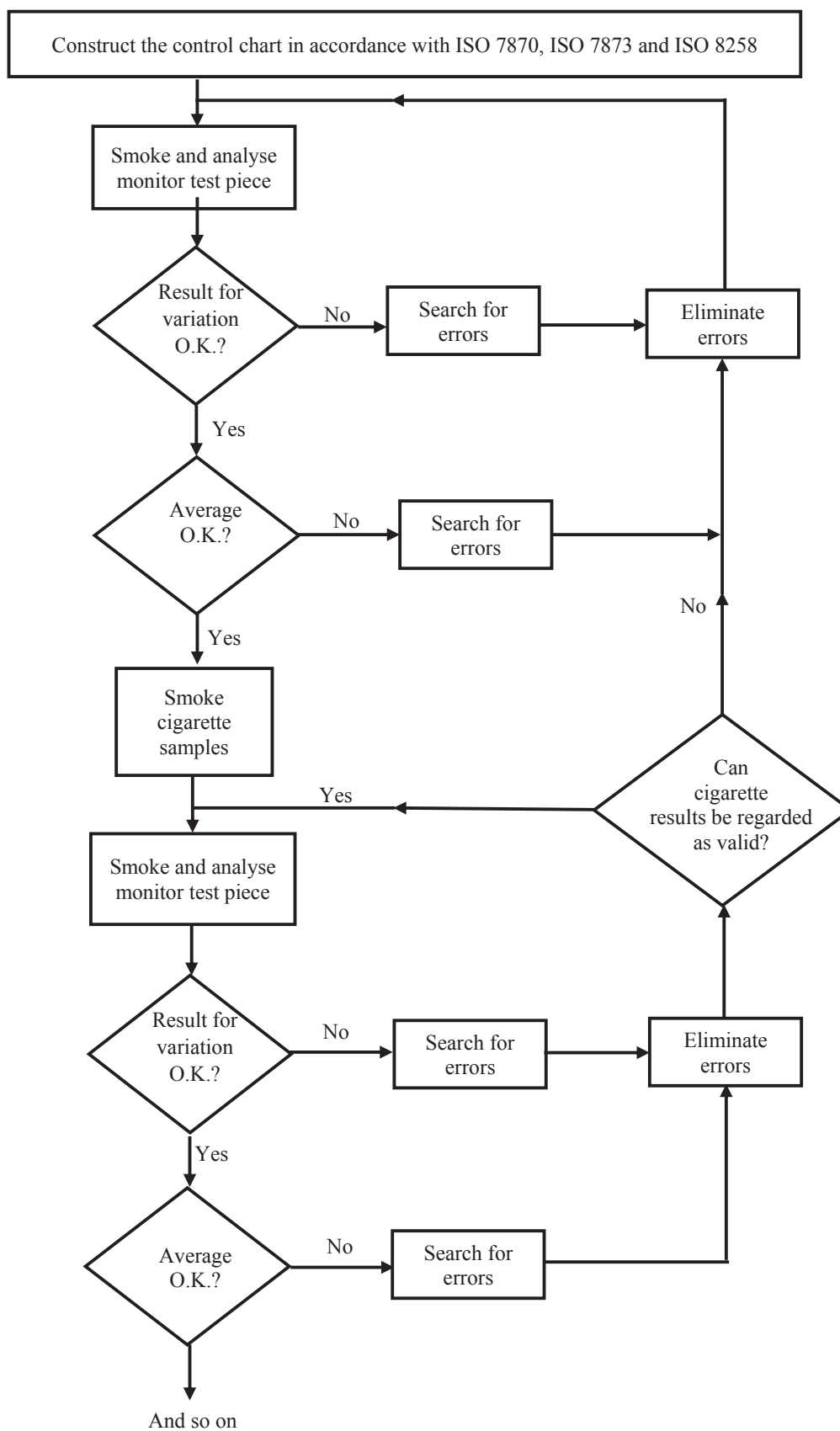


FIG. 1 FLOW CHART FOR THE USE OF MONITOR TEST PIECES IN ROUTINE ANALYTICAL SMOKING

**5.4** The monitor test pieces are periodically smoked in parallel to sample cigarettes on a linear smoking machine and sequentially on a rotary machine to maintain a check and control on the smoking machine and smoking process (*see* 7.2.2 and 7.2.3).

NOTE — The frequency of smoking test pieces as controls when sample cigarettes are being smoked will vary from laboratory to laboratory and from machine to machine. Practical procedures and suggestions are given in 7.2.3.

## 6 SHEET INFORMATION

### 6.1 General

A data sheet shall contain the information set out in 6.2 and 6.3.

### 6.2 General Specifications

**6.2.1 Physical** — Specifications for length, diameter/circumference, filter length, tipping length and filter material.

**6.2.2 Chemical** — Total sugar, reducing sugar and nicotine.

### 6.3 Analysis Values for Smoke Yields

The results from the laboratory testing of the monitor test piece, comprising:

- a) the type of smoking machine used;
- b) the average and standard deviation of the results for puff number;
- c) the average and standard deviation of the results for nicotine in the smoke;
- d) the average and standard deviation of the results for nicotine-free dry particulate matter;
- e) the average and standard deviation of the results for carbon monoxide in the smoke;
- f) the two-sided confidence interval for the mean values, with a confidence level of 95 percent.

## 7 USE

### 7.1 General

Monitor test pieces are used to monitor the stability of the analytical processes involved when using a cigarette-smoking machine for routine analyses in accordance with IS 16022. In particular, they are used to assess whether the analytical process related to the machine-smoking of cigarettes [described in IS 16121, IS 16023, IS 16024, IS 16025 and IS 16042-1 (or IS 16042 (Part 2))] is 'in statistical control' (*see* ISO 7870-1).

The routine use of monitor test pieces may vary from laboratory to laboratory and between the two commonly used types of analytical smoking machine. The general principle is to evaluate the consistency of the values of the essential parameters (such as puff number, carbon

monoxide in the vapour phase, total particulate matter, nicotine and water in total particulate matter and NFDPM) by using control charts.

Monitor test pieces are not to be used for calibration purposes, and the results obtained with monitor test pieces shall not be used for correcting or calculating analytical data from investigation samples.

The smoke yields will normally be based upon the smoking of at least 20 monitor test pieces as described in IS 16023.

The smoking of 20 cigarettes will give one average result from a rotary smoking machine whereas a linear smoking machine will give 4 average results from smoking 5 cigarettes in each of 4 channels. This means that the variation in the smoking process has to be determined by different methods for the two smoking machines. For the rotary machine, the variation may be determined as a 'between smoke runs' variation whereas the variation for the linear machine may be determined from the 4 individual results from the 4 channels. In other words, the process variation from the rotary smoking machine is based on 'independent' single results while the variation from the linear smoking machine can be based on 4 results from one smoke run but from 4 'independent' channels.

This means that different types of control chart have to be used for the two smoking machines. The actual choice shall be made according to the actual demands and cannot be specified to fit all needs.

### 7.2 Practical Procedures for the Use of Monitor Test Pieces

The practical procedures for use of monitor test pieces are based upon the condition that the consistency of a process can be evaluated by analysing control samples at chosen intervals, and comparison of the test results graphically in a control chart (*see* ISO 7870-1).

**7.2.1** The frequency at which the monitor test pieces shall be analysed cannot be specified. It depends on the local need. The considerations given in 7.2.2 and 7.2.3 describe the importance of a practical choice (*see also* ISO 7870-2 : 2013).

**7.2.2** Under the condition that the analytical process is consistent (stable), it is assumed that all the analytical results obtained between two valid results from the monitor test pieces are also valid. In contrast, results obtained during a period which begins with a valid check result and ends with a non-valid check result must be regarded as non-valid until further investigations have indicated their validity. Thus there is a risk of having to reject these results and having to repeat the analysis. To avoid the loss of large numbers of results, it is important to analyse the monitor test piece at intervals which are not 'too great'. It becomes a balance between analytical capacity and need for confirmation of consistency.

**7.2.3** The procedure for the two types of smoking machine will be different but based, of course, upon the same principle: sequential smoking and confirmation of the validity of the smoking results.

The following procedure can be recommended:

- a) *For the rotary smoking machine* — At the beginning of a series of smoking analyses, a smoking run and an analysis is performed with the monitor test pieces. At practical intervals (for example for each 10 to 15 smoke runs), this procedure should be repeated, ending the day with smoking of the monitor test pieces.
- b) *For the linear smoking machine* — At the beginning of a series of smoking analyses, the monitor test piece is smoked on a selection of channels (4 would normally fit into a smoking plan). During the daily smoking, this could be repeated at a practical frequency, with monitor test pieces being smoked on 4 channels for every 2 or 3 smoke runs. To secure the best information, it is important that smoking of the monitor test pieces is evenly distributed on all 20 channels over a period of time.

### 7.3 Practical use of Control Charts

The analysis values from smoking and analysis of monitor test pieces are plotted on the appropriate control charts so that the results for average and for variation can be evaluated.

It is possible to use control charts where standard values are given, but also where the standard values are not given (*see* ISO 8258). This means that control charts can be constructed for the individual laboratory without knowledge of the official target values for the test piece but the control chart can also be constructed with reference to target values.

The control charts may have both warning and action limits (*see* ISO 7873) or have only one set of control limits (*see* ISO 8258). Either kind of control chart can be used, but for the correct evaluation of the consistency of the analytical process it is very important that the rules for testing for assignable causes (*see* ISO 8258) are followed.

It is a matter of choice whether to use control charts with or without target values combined with one set or two sets of control limits. It depends on the actual needs. It may be practical to combine the target values from the inter-laboratory testing with the results from the individual laboratory's own routine check. On the other hand, this may be impractical for laboratories which have analytical averages which differ from the target values. In these cases, the consistency check will be affected by the obstruction of the control limits by the official target values, and it may be better to determine any difference between the local average and the official average by other statistical methods for differences between variances and between averages.

## ANNEX A

### CORESTA monitor test piece — Specification

**Table A-1 Tobacco Blend and Cut Rag**

| Parameter       | Description                                                     |
|-----------------|-----------------------------------------------------------------|
| Type of tobacco | Flue cured lamina without stems                                 |
| Additives       | Preferably none, but absolutely no more than 2 percent glycerol |
| Cut width       | ≈ 0.9 mm                                                        |

**Table A-2 Monitor Test Piece Dimensions**

| Parameter                | Value                    |
|--------------------------|--------------------------|
| Test piece length        | ≈ 83 mm (king size)      |
| Test piece diameter      | ≈ 7.8 mm                 |
| Test piece mass          | ≈ 980 mg                 |
| Test piece pressure drop | ≈ 1.4 kPa <sup>a)</sup>  |
| Rod length               | ≈ 62 mm                  |
| Rod mass                 | ≈ 820 mg                 |
| Tobacco mass             | ≈ 780 mg                 |
| Tobacco density          | ≈ 260 mg/cm <sup>3</sup> |
| Tobacco moisture         | ≈ 12.0 percent           |

<sup>a)</sup> Pressure drop may also be expressed in millimetres water gauge (mm WG). 1.4 kPa ≈ 140 mm WG.

**Table A-3 Monitor Test Piece - Non-tobacco Materials**

| Parameter            | Value                                                                                                                                                                                                                                                          |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Filter rod diameter  | ≈ 7.8 mm                                                                                                                                                                                                                                                       |
| Tow specification    | High-crimp cellulose acetate tow of type 2, 8Y36HK (dtex units) (in denier units 2, 5Y32HK) or similar                                                                                                                                                         |
| Filter pressure drop | In the range 0.75 kPa to 0.8 kPa <sup>a)</sup>                                                                                                                                                                                                                 |
| Plasticiser          | ≈ 7 % triacetin                                                                                                                                                                                                                                                |
| Plug wrap            | Non-porous                                                                                                                                                                                                                                                     |
| Filter length        | ≈ 21 mm                                                                                                                                                                                                                                                        |
| Tipping              | Distinguishable from commercial products (that is, grey tipping) with CM logo, no perforation preferable.                                                                                                                                                      |
| Tipping width        | ≈ 29 mm                                                                                                                                                                                                                                                        |
| Test piece paper     | Wood pulp, filler precipitated calcium carbonate ≈ 30 percent, air permeability ≈ (40 to 50) cm <sup>3</sup> min <sup>-1</sup> cm <sup>-2</sup> at a pressure differential of 1 kPa <sup>b)</sup> , citrate (expressed as anhydrous citric acid) ≈ 0.7 percent |
| Paper width          | ≈ 26 mm                                                                                                                                                                                                                                                        |

<sup>a)</sup> Pressure drop may also be expressed in millimetres water gauge (mm WG). 0.75 kPa to 0.8 kPa ≈ 75 to 80 mm WG.

<sup>b)</sup> Air permeability may also be expressed in CORESTA units (CU). 1 CU = 1 cm<sup>3</sup> min<sup>-1</sup> cm<sup>-2</sup>.

**Table A-4 Smoke Yields**

| Parameter   | Value                       |
|-------------|-----------------------------|
| NFDPM       | ≈ 14 mg/monitor test piece  |
| Nicotine    | ≈ 1.4 mg/monitor test piece |
| CO          | ≈ 14 mg/monitor test piece  |
| Puff number | ≈ 9                         |

## **ANNEX B**

### **BIBLIOGRAPHY**

- |                                                                                    |                                                                       |
|------------------------------------------------------------------------------------|-----------------------------------------------------------------------|
| 1 ISO 3402 Tobacco and tobacco products — Atmosphere for conditioning and testing. | 3 ISO 7870-2 : 2013 Control charts — Part 2: Shewhart control charts. |
| 2 ISO 7870-1 Control charts — Part 1: General guidelines.                          | 4 ISO 7873 Control charts for arithmetic average with warning limits. |
|                                                                                    | 5 ISO 8258 Shewhart control charts.                                   |

## ANNEX C

( Foreword )

## COMMITTEE COMPOSITION

Tobacco and Tobacco Products Sectional Committee, FAD 04

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### Amendments Issued Since Publication

| Amend No. | Date of Issue | Text Affected |
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